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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,158	02/21/2001	Rachel Louise Allen	P02077 US0	2564

26271 7590 03/11/2005
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EXAMINER

DIBRINO, MARIANNE NMN

ART UNIT PAPER NUMBER

1644

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/700,158

Applicant(s)

ALLEN ET AL.

Examiner

DiBrino Marianne

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1644, Group 1640, Technology Center 1600.

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-7, 20 and 30, drawn to a dimer/composition thereof

II. Claim 8, drawn to a method of making a dimer comprising providing 2 peptides under conditions in which they cross-link

III. Claims 9, 10, 11, 16 and 17, drawn to a method of detecting in a sample the presence of a receptor/determining the onset of or predisposition to a spondyloarthropathy, comprising contacting the sample containing the receptor with a dimer and measuring binding

IV. Claim 12, drawn to a monoclonal antibody comprising an epitope that binds a dimer

V. Claim 13, drawn to a method of determining the inhibition of binding of a dimer to an antibody by an inhibitor in a sample

VI. Claim 14, drawn to a method of determining the inhibition of binding of a dimer to a receptor by an inhibitor in a sample

VII. Claim 15, drawn to a method of treating a subject comprising administering to a subject a composition comprising a dimer

VIII. Claims 18, 19 and 28, drawn to an ex-vivo cell/composition thereof comprising a dimer

IX. Claim 21, drawn to a polynucleotide encoding a dimer

X. Claim 22, drawn to a transgenic non-human animal engineered to express a dimer

XI. Claims 23 and 27, drawn to a substantially isolated T cell capable of binding a dimer

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XII. Claims 24 and 25, drawn to a method of treating/tolerizing a human or animal to a native homodimer comprising administering a composition comprising a dimer

XIII. Claim 26, drawn to a method of treating a subject comprising administering a composition comprising an antibody that binds a dimer

XIV. Claim 29, drawn to a method of tolerizing a human or animal to a native homodimer comprising administering a composition comprising a cell that comprises a dimer

3. The inventions listed as Groups I-XIV do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claim 1 of the instant application does not provide a technical feature that is distinguished over the prior art, as evidenced by Capps et al (J. Immunology 151(1): 159-169, 1993, Applicant's IDS reference) or Allen et al (J. Immunol. 162: 5045-5048, 1 May 1999, Applicant's IDS reference).

Capps et al teach an HLA-B27/b2m dimer, which reads upon "a substantially isolated functional dimeric or multimeric analogue thereof which is capable of binding said HLA-B27 epitope and/or competes for binding to a specific receptor for said dimer" recited in instant claim 1.

Allen et al teach the HC-27 HLA-B27 heavy chain homodimer. Because Applicant's foreign priority document UK 9810099.2 filed 5/11/99 is has not been provided in the instant application, and thus the Allen reference has a publication date prior to the 371 filing date of PCT/GB99/01481 of 5/11/99.

Therefore, the instant invention lacks Unity of Invention.

4. **Irrespective of whichever group Applicant may elect**, Applicant is further required to (1) elect a single disclosed species of (a) for product claims: a specific dimer, or polynucleotide encoding a specific dimer, or specific cell comprising a specific dimer, or a transgenic animal comprising a specific dimer, or an antibody that binds a specific dimer; (b) or for method claims: a specific dimer, or polynucleotide encoding a specific dimer, or specific cell comprising a specific dimer, or a specific antibody that binds a specific dimer, to be used in a claimed method (for example, if the Invention of Group I is elected, a dimer of the extracellular portion in which the first polypeptide consists of amino acid residues 1-275 of HLA-B27 heavy chain cross-linked by a disulfide bond between Cys 67 of each polypeptide or for example, HC-B27) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

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These species are distinct because their structures are different.

5. **In addition, If Applicant elects the Invention of Group III,** Applicant is further required to (1) elect a single disclosed species of receptor (for example, TCR specific for HLA-B27) to which claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. 809.02(a).

9. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103 of the other invention.

10. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

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12. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Christina Y. Chan, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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March 4, 2005



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